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Regulatory Council

Statement on Regulation of Chemical Carcinogens; Policy and Request for Public Comments

REGULATORY COUNCIL

Statement on Regulation of Chemical Carcinogens; Policy and Request for Public Comment

AGENCY: Regulatory Council.

ACTION: Notice of Policy and Request for Public Comment.

SUMMARY: This policy is being published in the **Federal Register** to inform the public of the practices and principles the participating Federal regulatory agencies will follow in initiating regulatory actions relating to chemical carcinogens.

The Regulatory Council would welcome any comments from the public, particularly any additional information pertinent to these policies which may have been considered in the preparation of the statement.

Because much of the scientific basis for the policies on identifying chemical carcinogens and assessing human risk relies on the analyses and discussion in the document "Scientific Bases for Identification of Potential Carcinogens and Estimation of Risks," published at 44 FR 39858, July 6, 1979 (Annex B to this document), we request potential commenters to read that document carefully before commenting on the *scientific issues* addressed in the Regulatory Council's statement. We would further suggest that any comments on the substance of Annex B be addressed directly to that document which is currently undergoing public review and comment as well. The comment period on that document is being extended to October 31 by separate notice to allow additional comments to be received.

DATES: We would appreciate receiving comments by November 15, 1979, to ensure speedy consideration of additional public views.

ADDRESS: Mail comments to: Regulatory Council, Attention: Cancer Policy, Room 5002, New Executive Office Building, Washington, D.C. 20503.

Copies of this document including Annex B are available from: Industry Assistance Office, Office of Toxic Substances (TS–799), U.S. Environmental Protection Agency, 401 M Street, SW., Washington, D.C. 20460; or

Call toll-free 800/424–9065. In Washington, call 554–1404.

Signed in Washington, D.C., this 11th day of October 1979.

Peter J. Petkas,

Director.

Regulation of Chemical Carcinogens, September 28, 1979.

Statement on Regulation of Chemical Carcinogens

Introduction.
Determining Whether a Chemical Substance May Cause Cancer.
Assessing the Risk of Cancer to Humans.
Setting Priorities for Regulating Carcinogens.
Considering Regulatory Action.
Federal Agencies Having Primary Roles in the Regulation of Chemical Carcinogens, Annex A.
Scientific Bases for Identification of Potential Carcinogens and Estimation of Risks, Annex B.
Interagency Coordination Efforts Currently Underway Relevant to the Regulation of Carcinogens, Annex C.

Statement on Regulation of Chemical Carcinogens

Introduction

Cancer is a major national public health problem. Various kinds of cancer currently claim almost 400,000 lives per year, second only to heart disease, and a million people are under treatment for some form of the disease. One in four Americans—an average of almost one person per family—can expect to develop cancer in his or her lifetime, one in five will eventually die of it.

Cancer is also a substantial economic burden. The National Center for Health Statistics estimates that by 1977 the Nation was spending $5.5 billion each year on hospital care and physicians' services for cancer patients, and that the expected earnings of people who died that year had a value of $14.6 to $18.5 billion.

In addition, there are substantial social costs that are more difficult to quantify. The cancer victim may be disabled and in substantial pain even if he or she survives the disease. The victim's family may be left financially destitute and socially isolated, and may not recover from the psychological and economic costs related to the disease.

Encouraging advances are being made in treating some forms of cancer, so that more victims are now living five or more years after the disease is discovered. But progress in cancer treatment is slow because of the many gaps in our basic scientific knowledge about the disease.

The Nation, therefore, must make a particularly strong effort to prevent various kinds of cancer. With our present knowledge, this can be done most effectively by preventing the exposure of people to cancer-causing agents. There is substantial evidence that environmental factors are among the major causes of at least some kinds of cancer. Environmental factors include potential cancer-causing substances (called carcinogens) in food, air, drinking water, tobacco products, workplaces, drugs, and household products, as well as radiation (including ultraviolet light). In many instances people are exposed unknowingly to these factors and have little or no power to prevent such exposure.

To provide effective means of dealing with these problems, the Congress has enacted a number of laws under which several Federal agencies are empowered to prevent or limit human exposure to carcinogens. Annex A lists the Federal agencies primarily involved in such activities and briefly describes their authority to regulate carcinogens (excluding radiation, which is not covered in this policy statement). Because of the number of different agencies that are involved in the effort to control cancer, many people in the Administration, in Congress, and in the general public have become concerned about possible inconsistencies, duplication of effort, and lack of coordination which could make the attack on cancer less effective and more expensive than it need be.

Avoiding such problems has been one of the major priorities of this Administration. To this end, President Carter established the Regulatory Council in October 1978 to promote improved coordination of regulatory activities and to help ensure that regulatory objectives are achieved in a cost effective manner. Because of the importance of cancer in our society and the need to ensure that we control it effectively and efficiently, the President asked the Regulatory Council, as one of its first projects, to develop a statement setting forth the policies to be followed by regulatory agencies in their efforts to prevent or limit human exposure to carcinogens. This document is the product of that effort.

It in turn relies substantially upon an earlier effort undertaken by four of the regulatory agencies—the Environmental Protection Agency, Food and Drug Administration, Occupational Safety and Health Administration, and Consumer Product Safety Commission (recently joined by the Food Safety and Quality Service). Two years ago, the heads of these agencies formed the Interagency Regulatory Liaison Group (IRLG) to improve the public health through sharing of information, avoiding duplication of effort, and developing consistent regulatory policy.

Recognizing the importance of coordinating their regulation of cancer-causing chemicals, the agency heads asked key scientists and other staff from their agencies, the National Cancer Institute, and the National Institute of Environmental Health Sciences to prepare a document setting forth the scientific bases for making regulatory decisions on carcinogens. This group prepared a document entitled "Scientific Bases for Identification of Potential Carcinogens and Estimation of Risks" (attached as Annex B) which represents the best judgment of the participating scientists on the scientific principles applicable to identifying and evaluating substances that may pose a risk of cancer to humans.

The Regulatory Council's assignment was to consider the scientific issues addressed in the IRLG document along with the many other aspects of the government's efforts to regulate carcinogens, and to prepare a government-wide policy which reflected this Administration's actions to promote more effectively the public health without imposing unnecessary burdens upon the economy, and to eliminate potential inconsistencies and inefficiencies in the government's regulatory programs.

In carrying out this assignment the Council took account of not only the IRLG document, but many other reports and activities relating to the government's effort to control cancer. These included reports by the President's Office of Science and Technology Policy and the interagency Toxic Substances Strategy Committee, the analyses and comments relating to the Occupational Safety and Health Administration's proposed cancer policy, and the activities of the National Toxicology Program, the National Institutes of Health, and the National Cancer Advisory Board.

Although the preparation of this statement benefited from all of these efforts, it is based most substantially upon the document prepared by the IRLG. That document, attached as Annex B, should be referred to for additional information. The IRLG document has undergone scientific peer review and is currently receiving public comment; any changes made in it as a result of the review and comment process will be incorporated into this policy.

There are many important aspects of the government's efforts to reduce the seriousness of the problem of cancer in our society. These range from basic research on the biology and causes of cancer, through efforts to improve the diagnosis and treatment of the disease, to the rehabilitation of cancer victims. The focus of the Regulatory Council, however, was on issues relating to the efforts of the regulatory agencies to limit people's exposure to cancer-causing substances. Here the Council carefully reviewed the different components of the regulatory process, and the current efforts to coordinate activities in each (Annex C). As a result, it concluded that the predominant need for clarification and coordination was limited to the following four major areas of activity relating to the regulation of chemical carcinogens:

- Determining whether a chemical may cause cancer.
- Assessing the risk of cancer to humans.
- Establishing regulatory priorities.
- Undertaking regulatory activities.

These are the four areas addressed in this policy statement. An agency's actions within these areas are, of course, determined by the specific language in the applicable Federal law. However, there are many common issues which all the agencies have to deal with. This statement briefly summarizes the concepts and principles that the regulatory agencies will generally follow in each of the four areas, consistent with substantive and procedural legal constraints, in initiating regulatory action. The members of the Council do not consider this statement in any way to alter their obligations to reach decisions based upon information in the record of the particular action involved.

Determining Whether a Chemical Substance May Cause Cancer

The first step in regulating a substance as a carcinogen is to examine and evaluate the evidence that it may cause or contribute to the occurrence of human cancer. The two principal sources of such evidence are epidemiological studies involving people exposed to the substance, and testing in laboratory animals.

It is important that the regulatory agencies make such evaluations in accordance with current scientific thinking and in a consistent manner. The IRLG document "Scientific Bases for Identification of Potential Carcinogens and Estimation of Risks" is a significant step in this direction. One portion of this document describes the basis for making qualitative evaluations of whether a particular substance presents a carcinogenic hazard, and how the results of epidemiological studies and animal testing, along with other types of information, are used in making these evaluations.

Regulatory agencies will base their determinations of whether a substance is likely to be carcinogenic upon a rigorous evaluation of all relevant, available scientific evidence. Epidemiological studies or animal tests provide the best evidence of carcinogenicity, but other types of information can also be important. Although they cannot be adequately summarized in a few sentences it is important that there be a general understanding of several basic concepts involved in these evaluations.

Epidemiological Studies. Properly designed and conducted epidemiological studies showing a significant satistical relationship between human exposure to a substance and an increased occurrence of cancer in the exposed population are considered to provide good evidence that the substance is carcinogenic.

In the past many people argued that such studies should be considered a prerequisite to undertaking any significant regulatory action. There are, however, limitations on the usefulness of epidemiology. Everyone is exposed to many chemicals in his or her lifetime. And cancer may not occur until 30 years or more after exposure to a carcinogen. Thus, there may be a substantial delay, allowing many additional people to be exposed, before any epidemiological evidence can be obtained. Even then, it may be very difficult to associate the occurrence of cancer with exposure to specific chemicals may years previously. Epidemiological studies often cannot detect even large increases (which could involve thousands of people) in the occurrence of cancer resulting from exposure to chemicals. For these reasons:

- The failure of an epidemiological study to detect an association between the occurrence of cancer and exposure to a specific substance should not be taken to indicate necessarily that the substance is not carcinogenic.
- Because it is unacceptable to allow exposure to potential carcinogens to continue until human cancer actually occurs, regulatory agencies should not wait for epidemiological evidence before taking action to limit human exposure to chemicals considered to be carcinogenic.

Testing in Animals. Properly designed and conducted tests in laboratory animals also provide good evidence of a substance's potential human carcinogenicity. From a biological standpoint the development of cancer is similar in humans and animals, even though different species and different strains of a species may demonstrate different sensitivities to specific

substances. Because we cannot test substances in humans or wait for demonstrations of carcinogenicity from epidemiological studies, Federal agencies must continue to use animal tests to identify chemical substances that may cause human cancer. In interpreting and applying the results of these tests they should use the following precepts unless there is substantial scientific or legal reason not to:

- A substance that causes cancer in animals, when tested under appropriate conditions, will be considered a potential human carcinogen.
- Animal tests provide valid information even though the dosage administered to the animals may be higher than humans are likely to experience. Animals are given relatively high doses both to increase the sensitivity of the test by maximizing the likelihood that a cancer-causing substance will actually produce cancer, and to compensate for the relatively small numbers of animals typically used in the tests. Although the likelihood of detecting a carcinogenic effect and the time between exposure to the carcinogen and the occurrence of cancer may be related to the dose level tested, the intrinsic ability of a substance to induce cancer is independent of dosage. A noncarcinogen can be toxic when administered in high doses, but it will not directly cause cancer at any dose level. In fact, the majority of chemicals tested in animals, even at high doses, has not been found to be carcinoginic.
- Evaluation of the results of animal testing is simplified when the animals are exposed by the same route by which people are or will be exposed, but the results are also relevant to human risks where exposure is by a different route. For instance, if a substance causes cancer when tested by ingestion, there is good reason to expect it to be able to cause cancer when inhaled.
- In evaluating results of animal tests, the occurrence of benign tumors in the treated animals is an indication that the substance being tested may produce malignant tumors as well. Benign tumors often are a precursor stage of malignant growths. Furthermore, virtually all extensively tested chemicals that have produced benign tumors have also produced malignant tumors.
- If a substance has been shown to be carcinogenic under the conditions of a single properly designed and conducted test, it should be considered as posing a risk of cancer to humans. Although the agencies should attempt to obtain additional data, they should not take the risk involved in waiting the two to four years required to complete an additional animal bioassay before initiating regulatory action.
- Evidence that a chemical is a carcinogen is strengthened by test results indicating carcinogenicity under two or more tests or test conditions (for example, at two or more dose levels, in both sexes, or in two or more animal strains of species). Similarly, evidence that a substance is not a carcinogen is strengthened if there is a lack of carcinogenic response in two or more properly disigned and conducted tests.
- In cases where there are conflicting results from more than one properly designed and conducted test, results failing to demonstrate a carcinogenic response do not detract from the validity of results showing such a response if different species of animals were tested, and they do not ordinarily detract from such results if the same species were tested. Even known carcinogens would be expected to show no response in some tests, particularly, for instance, when relatively few animals are involved, dose levels are low, or an insensitive animal strain is used.

Other Types of Evidence. In recent years there has been encouraging progress in developing certain short-term screening tests (involving animals, mammalian cells, or micro-organisms) and in using chemical structure to predict carcinogenic potential. Such approaches may provide a substantially faster and less expensive way of obtaining evidence on a substance's potential carcinogenicity. Such evidence, although currently only considered suggestive, can properly be used for the following purposes:

- To help identify chemicals that should be more thoroughly tested.
- To help in planning priorities for regulatory actions.
- To buttress evaluations of the results of long-term testing in animals.
- To support regulatory actions dealing with groups of substances having similar chemical or biological properties.

Testing Policy: Because long-term testing in animals is so important in evaluating the cancer-causing potential of chemical substances, and because such testing is time-consuming and expensive and requires scientific expertise and specialized facilities, it is essential that it be performed as efficiently as possible. The current government policy on such testing is that:

- The primary responsibility for much of this testing, as specified in several Federal laws, lies with the firms involved in manufacturing chemical substances. Agencies having the authority to do so should ensure that any required testing is carried out properly and as expeditiously as possible.
- The Federal regulatory agencies specify the chemicals to be tested and the testing procedures to be used by industry, and ensure industry compliance with testing requirements. they also cooperate with the Federal research agencies responsible for basic research on cancer causes and treatment, to support the development and validation of new testing procedures, and to perform testing (as well as epidemiological studies) in certain circumstances, for instance, where it is not practical to rely on industry to do so or where an agency is not authorized to impose such requirements on industry.
- Although a substance may sometimes need to be tested more than once to assess its potential carcinogenicity under differing conditions, regulatory agencies will avoid, whenever possible, imposing duplicative or conflicting testing requirements. The IRLG agencies are already preparing testing guidelines to accomplish this goal.

Assessing the risk of cancer to humans

After it has been determined that a chemical substance is likely to be carcinogenic, the next step in regulatory decision-making is to assess the risk that people face of developing cancer from their exposure to the substance.

Contents of Risk Assessments. All risk assessments contain two basic components. The first is an analysis of the evidence of the carcinogenicity of the substance, and the second is an analysis of the human exposure to the substance in order to assess the health risk it may pose.

The analysis of the carcinogenicity as described in the preceding section of this statement, involves a determination of whether a substance is likely to cause cancer in humans, accompanied by a characterization of the extent and quality of the evidence supporting this determination. It may also include an analysis of the relationship between the observed carcinogenic effects and the dose levels used in animal tests or the apparant levels of exposure in epidemiological studies.

The analysis of human exposure involves at least an estimate of the size of the exposed population, and may also include such factors as exposure sources, routes, and conditions, the duration, frequency, and intensity of exposure, and the relevant characteristics (e.g., age, sex, health) of the exposed population. The agencies will use exposure measurements when

they are available and reliable; otherwise, they should estimate exposure based upon reasonable assumptions and interpretations of the best data available, which may be limited to information on the manufacture, use, or environmental discharge/disposal of the chemical substance in question.

Although all risk assessments include these two basic components (analyzing the evidence of carcinogenicity and likely human exposure) the form, methodology, and elaborateness of the assessment may vary substantially. Depending upon the characteristics and extent of the available information and on the regulatory agency's specific needs, the range of approaches varies from quantitative estimates of the increased human risk of developing cancer to nonquantitative assessments of relevant epidemiological and/or testing data and evidence that people are likely to be exposed to the substance.

Risk Assessment Precepts. When undertaking risk assessments, the regulatory agencies will follow the following precepts:

- Except where a statute, as in the case with the Clean Water Act, explicitly indicates which substances are to be controlled and how, every regulatory proposal will be accompanied by some form of risk assessment which includes, at a minimum, an analysis of the evidence of the substance's carcinogenicity and a determination that people are likely to be exposed to the substance.
- The particular form and type of risk assessment undertaken will depend upon the suitability of the available information to support different types of analyses, and upon the amount of information the agency needs to support proposed regulatory actions.
- Because there is no currently recognized method for determining a no-effect level for a carcinogen in an exposed population, substances identified as carcinogens will be considered capable of causing or contributing to the development of cancer even at the lowest doses of exposure.

Where the available data are scientifically adequate to support them, quantitative risk estimates can provide useful information for proposed regulatory decisions. When they make such estimates in initiating regulatory actions, the agencies will use the procedures described in the IRLG document "Scientific Bases for the Identification of Potential Carcinogens and Estimation of Risks".

- However, quantitative risk estimates are not yet sufficiently developed to be regarded as more than rough indicators of the level of human risk. The sources of uncertainty include, for instance, the difficulties of extrapolating from one population group to another, from high doses to low doses, and from animals to man, and the impossibility of identifying or considering all the factors that affect the response of people to exposure from specific carcinogenic substances.
- In certain instances, it is impractical or unnecessary to make quantitative exposure or risk estimates. This may be true when it is impossible to predict what exposure may occur, in dealing with complex chemical mixtures of unknown or varying composition where it is not feasible to regulate each of the constituents independently, or when regulatory action is concerned with substances to which the population is exposed through a multitude of sources or products at different levels and in different ways.
- If they undertake quantitative estimates of risk, agencies will attempt to identify the range of risk that could, on the basis of available information, reasonably be associated with possible exposure to the substance. Because underestimating cancer risks could have serious public health consequences, the agencies will in particular attempt to estimate the maximum risk that could reasonably be expected.
- Because all risk assessments, whether quantitative or not, necessarily involve substantial degrees of uncertainty, they will be accompanied by statements discussing these uncertainties.

Setting priorities for regulating carcinogens

A substantial number of cancer-causing chemicals has already been identified. As other chemicals are tested, some of them also are likely to be found capable of producing cancer. In deciding which ones to regulate first, Federal agencies will generally assign higher priorities to substances for which:

- There is substantial evidence that the substance is likely to present a risk of human cancer. Epidemiological studies and/or animal testing are sources of such evidence.
- There is reason to believe that the level of human exposure and/or risk is high. Either quantitative or nonquantitative risk assessments may provide a basis for such belief.
- The exposed population is large or is of special concern, such as children.
- Regulatory action could significantly reduce the extent of intensity or human exposure.
- Regulatory action could reduce not only cancer risk but also other human health and environmental hazards.
- A substance is, or could be, available that would pose a lower risk of cancer or other serious human health problems, or available evidence otherwise suggests that the social and economic costs of regulation would be small.

The relative importance of these priority-setting criteria will necessarily vary from case to case, and in establishing their final priorities the agencies also consider:

- The requirements of applicable laws or court orders which may limit their flexibility to establish their own priorities
- Their responsibilities for dealing with other health and environmental hazards
- The regulatory actions being taken or planned by other agencies.

Although the agencies will continue to coordinate their regulatory actions, each agency will establish its own regulatory priorities. Specific substances usually are not equally important from the standpoint of every agency's statutory mission. As an example, one substance may provide a serious risk to workers, but very little in consumer products. Another, however, might provide a serious risk in consumer products, but present little risk to workers. The most effective public health protection would occur if the agency concerned with protecting workers gives the former a higher priority and the agency concerned with protecting consumers gives the latter a higher priority.

In general, the regulatory programs will provide the most public health protection if each agency dealing with a specific area of exposure places the highest priority on the substance which provides the greatest health risk in its area of concern. Otherwise, agencies might be regulating substances which are of relatively little importance in their area of concern, creating unnecessary regulations and costs, with little public health benefit, and putting off actions which would provide much more benefit. For these reasons, it is neither necessary nor desirable that all agencies assign the same priority to each substance.

Considering Regulatory Action

Federal laws governing the regulatory programs often prescribe the factors to be considered in choosing among regulatory options and deciding how extensive and stringent regulatory

action should be. In many instances, however, regulatory agencies have latitude to interpret and apply the statutory language.

Bases for Regulatory Action. In brief, regulatory decisions generally are based upon one or some combination of the following approaches:

• *Risk.* A few statutes require agencies, when making a regulatory decision, to consider solely or primarily the risk a substance poses. If a statute requires the elimination of risk, this can be accomplished only by eliminating human exposure, because there is no known way to identify levels below which exposure to cancer-causing substances presents no risk.

• *Technical and Economic Feasibility.* Various Federal laws require that regulatory decisions be based solely or primarily upon the technical and/or economic feasibility of controlling the release of or human exposure to cancer-causing substances. The stringency sought in such feasibility-based standards is stated in the applicable law—for example, "best available technology." The statute's language determines how an agency chooses among technologies capable of reducing environmental releases of (or human exposure to) chemical substances, and whether and how it considers associated economic and other impacts in making this choice. In some instances the technological standard is also determined by requirements to achieve certain ambient exposure levels.

• *Comparing Costs and Benefits.* Various statutes permit or sometimes require regulatory agencies to ensure that the economic and social costs of regulatory action are taken into account along with the expected risk reduction. Such statutes may refer to consideration of either the costs and benefits of regulatory action or the risks a substance poses and the benefits it provides.

In some statutes, Congress, after considering the advantages and disadvantages of these different approaches, has specified that one of them be used. For instance, Congress enacted a section of the Food, Drug and Cosmetic Act that requires the Food and Drug Administration to prohibit the use of any food additive found to be carcinogenic which presumably reflected a judgment that, among other considerations, the seriousness of the risk posed by carcinogenic food additives would exceed the benefits they provide and the costs associated with not using them; while a statute enacted to regulate pesticides indicates that the agency must take into account "the economical, social, and environmental costs and benefits" associated with the pesticide's use.

The fact that cancer-causing substances enter the environment and come into contact with people by various routes means that no single regulatory approach is equally suitable for dealing with cancer-causing substances in media as different as foods, drugs, household products, workplaces, air, and drinking water. Accordingly, it is, and will continue to be, necessary for Federal regulatory agencies to make appropriate use of different regulatory approaches when making regulatory decisions.

Regulatory Principles. The agencies nevertheless will follow several common regulatory principles. These principles will ordinarily guide the agencies in initiating regulatory actions, but they will not be rigidly and uniformly applied in all cases.

• In some cases, zero risk will be an appropriate regulatory goal. It is established as such in a few national policies and statutes. It is also an appropriate goal where (e.g., in controlling specific commercial products or specific types of discharges) the economic and social costs of regulation are so slight that almost any risk would be unreasonable. This might be the case, for instance, when there are several available substitutes for the substance being regulated which are no more costly than that substance and which create no known health risks.

• Zero risk will not routinely be considered achievable. For carcinogens, existing scientific knowledge indicates that zero risk requires zero exposure. But cancer-causing substances often occur in so many different consumer products, industrial raw materials, and commerical and industrial wastes that completely eliminating exposure, even if possible to do so, could, in many cases, have unacceptable economic, social and even health impacts.

• When planning a major regulatory action, in keeping with Executive Order 12044 and other Administration regulatory reform initiatives, agencies will analyze the economic consequences of proposed regulations, will identify and consider alternatives that would achieve their health protection goals, and, to the extent consistent with applicable laws, will choose the alternative that achieves their goals with the least economic and social costs.

• In limiting a substance's use, it is sometimes appropriate to consider other products or processes which might be adopted as a substitute for the substance being regulated. In these cases, one of the factors the agencies will consider, to the extent practicable, in making their regulatory decision is the health hazards associated with such substitutes.

• To avoid conflict and duplication, if several agencies are planning to adopt regulations controlling a specific substance or problem, they will coordinate the development of their regulations. The IRLG and the Regulatory Council have already adopted mechanisms to promote such coordination.

These principles are generally in accord with the requirements of Executive Order 12044. Federal agencies have elsewhere described the specific procedures they follow in analyzing and documenting the probable environmental, public health, economic, technological, and other impacts of proposed regulations and in providing opportunities for public participation.

Further Actions. Agencies responsible for regulating carcinogens have and will continue to identify and evaluate ways of improving their regulatory programs. Among other possibilities, they have considered or will consider, when appropriate, adopting generic policies for regulating carcinogens. Some are also evaluating the advantages and disadvantages of taking interim regulatory action to reduce high exposures to cancer-causing chemical before they undertake the usually time-consuming task of establishing permanent standards and regulations.

In general, the agencies should continue their efforts to develop carcinogen regulatory programs which will effectively protect public health without imposing unnecessary or unreasonable burdens upon the economy. In this process they should ensure that their actions are consistent and coordinated, and that the public has substantial opportunity to contribute.

Annex A to Statement on Regulation of Chemical Carcinogens

Federal Agencies Having Primary Roles in the Regulation of Chemical Carcinogens

Regulatory Agencies

Consumer Product Safety Commission (CPSC)

The purpose of the Consumer Product Safety Commission is to protect the public against unreasonable health and injury risks from consumer products; to assist consumers to evaluate the comparative safety of consumer products; to develop uniform safety standards for consumer products and minimize conflicting State and local

regulations; and to promote research and investigtion into the causes and prevention to product-related deaths, illnesses, and injuries.

The Commission assesses the health risks associated with the use of potential carcinogens in consumer products, and has the authority to restrict or prohibit uses considered to provide an unreasonable risk. It also sponsors some research on carcinogenic substances.

The statutes defining CPSC's responsibilities for regulating carcinogens and other toxic substances include The Federal Hazardous Substances Act (1966), The Consumer Product Safety Act (1972), and The Poison Prevention Packaging Act (1970).

Environmental Protection Agency (EPA)

The purpose of the Environmental Protection Agency is to protect and enhance our environment by controlling pollution in the areas of air, noise, radiation, and toxic substances.

EPA regulates potential carcinogens under several statutes, controlling their release into the air and water, their disposal as solid or liquid wastes on land and in the ocean, their occurrence in drinking water supplies, and their use in pesticides. It also is responsible for developing national strategies for controlling the general production and use of such substances and with coordinating these activities with other agencies. EPA also conducts and sponsors research on how chemicals are transported through and modified by the environment and on the carcinogenic potential of selected substances.

The statutes defining responsibilities for regulating carcinogens and other toxic substances include The Toxic Substances Control Act (1976), The Clean Air Act (1970, amended 1977), The Clean Water Act (as amended in 1972 and 1977), The Safe Drinking Water Act (1974, amended 1977), The Federal Insecticide, Fungicide, and Rodenticide Act (1947, amended 1972, 1975, 1978), The Act of July 22, 1954 (codified as section 346(a) of the Food, Drug, and Cosmetic Act) (1954, amended 1972), and The Resource Conservation and Recovery Act (1976).

Food and Drug Administration (FDA) (U.S. Department of Health, Education and Welfare).

The purpose of the Food and Drug Administration is to protect the health of the Nation against impure and unsafe foods, drugs, cosmetics, and other potential hazards.

FDA regulates the composition, quality, and safety of foods, food additives, food contaminants, colors, human and animal drugs, medical devices, and cosmetics. It must, by law, prohibit the use of any food additive found to be a carcinogen. It also conducts and sponsors research on the carcinogenicity of food contaminants, cosmetics, and other substances, and on the development of better methods for detecting the carcinogenic potential of regulated substances. FDA also develops methods to detect the presence of these substances in consumer products and monitors them to ensure their compliance with regulations.

The statutes defining FDA's responsibilities for regulating carcinogens and other toxic substances include The Food, Drug, and Cosmetic Act (1938) with its amendments pertaining to food additives (1958), color additives (1960), new drugs (1962), and new animal drugs (1968); The Fair Packaging and Labeling Act (1976); and The Public Health Service Act (1944).

Food Safety and Quality Service (FSQS) (U.S. Department of Agriculture).

The purpose of the Food Safety and Quality Service is to provide assurance to the consumer that foods are safe, wholesome, and nutritious; that they are of good quality; and that they are informatively and honestly labeled; and to provide assistance to the marketing system through purchase of surplus food commodities and those needed in the National Food Assistance Programs.

The FSQS inspects and controls the production of meat, poultry, eggs, and dairy products to ensure, among other things, that they are not contaminated with carcinogenic substances. The statutes defining FSQS's responsibilities for regulating carcinogens and other toxic substances include The Federal Meat Inspection Act (1967), The Poultry Products Inspection Act (1957), and The Egg Products Inspection Act (1970).

Occupational Safety and Health Administration (OSHA) (U.S. Department of Labor).

The purpose of the Occupational Safety and Health Administration is to ensure, so far as possible, safe and healthful working conditions for every working man and woman in the Nation.

OSHA assesses the health risks to workers associated with the use of carcinogenic substances in the workplace, and regulates the release of and concentration of carcinogenic substances that can occur in the workplace. It also monitors job related illnesses and informs workers of the potential hazards associated with specific substances found in the workplace.

The statute defining OSHA's responsibilities for regulating carcinogen and other toxic substances is the Occupational Safety and Health Act (1970).

Materials Transportation Bureau, Federal Railroad Administration, U.S. Coast Guard (U.S. Department of Transportation).

Among its many other activities, the Department of Transportation also has the responsibility to protect the public's health and safety when hazardous materials are transported.

The Materials Transportation Bureau was established to coordinate the agency's overall responsibilities concerning the regulation of hazardous materials transportation. It has the primary responsibility for promulgating regulations for all modes of transportation and for all aspects of regulating intermodal transportation of such substances. Among their other activities, the Federal Railroad Administration implements the regulations concerning the transportation of explosives and other dangerous articles by railroads, the U.S. Coast Guard implements the regulations covering the transportation of hazardous substances by water, and the Federal Highway Administration implements them for highways.

The major statutes defining the agency's responsibilities are The Hazardous Materials Transportation Act (1970), The Federal Railroad Safety Act (1979), The Port and Waterways Safety Act (1972), and The Dangerous Cargo Act (1952).

Research Institutes

National Cancer Institute (NCI) (National Institutes of Health, U.S. Department of Health, Education and Welfare).

The purpose of the National Cancer Institute is to expand scientific knowledge on the causes, prevention, diagnosis, and treatment of cancer in order to eliminate this disease as a national health problem.

NCI conducts and sponsors research on the origin, causes, and spread of cancer and on methods for diagnosing, preventing, and treating cancer. It conducts animal tests and epidemiological studies to identify carcinogens and research directed at developing improved testing methods for identifying carcinogens. It also, through its cancer control element, applies research findings to prevent, control, and treat human cancer and to rehabilitate cancer victims.

National Institute of Environmental Health Sciences, (NIEHS) (National Institutes of Health, Department of Health, Education and Welfare).

The purpose of the National Institute of Environmental Health Sciences is to

provide information on the impact of environmental factors on human health in order to aid those agencies charged with devising and instituting control or therapeutic measures.

NIEHS supports and conducts basic research focused upon the interaction between man and potentially toxic or harmful agents in his environment. This research is concentrated upon recognizing, identifying, and investigating the environmental factors that may have deleterious effects on population groups, on quantifying those efforts, and on understanding the mechanisms of action of toxic agents on biological systems.

National Institute of Occupational Safety and Health (NIOSH) (Center for Disease Control, Public Health Service, U.S. Department of Health, Education and Welfare).

The purpose of the National Institute of Occupational Safety and Health is to conduct research on and develop standards for occupational safety and health to ensure safe and healthful working conditions for all working people.

NIOSH conducts epidemiological, laboratory testing, exposure and source characterization studies on potential carcinogens found in the workplace. It also develops methods for monitoring the presence of carcinogens and for testing worker protection equipment and makes recommendations to OSHA regarding standards that should be applied to control workplace exposure and protect workers' health.

Annex B to Statement on Regulation of Chemical Carcinogens

Scientific Bases for Identification of Potential Carcinogens and Estimation of Risks

A Report Prepared by the Interagency Regulatory Liaison Group Work Group on Risk Assessment

Annex B is filed with the Office of the Federal Register as part of the original document. See 44 FR 39858, July 6, 1979.

Annex C to Statement on Regulation of Chemical Carcinogens

Interagency Coordination Efforts Currently Relevant to the Regulation of Carcinogens

There are a number of different mechanisms in existence for the purpose of promoting coordination among the agencies. Some of these have been established legislatively, others are imposed by the President or his staff, and others have been created by the agencies themselves.

An example of legislative coordination mechanisms would include provisions in several of the health and safety statutes which require the implementing agency to consider the views of or work done by other agencies and the appropriateness and advantage of deferring to other agencies authorities to address a particular problem.[1]

Another example of legislated coordination is the National Cancer Advisory Board (NCAB) established by the National Cancer Act of 1971 (as amended) to assist the Director of the National Cancer Institute with respect to a "National Cancer Program," and to review applications for funds to conduct cancer research. The 1978 amendments to this Act included the heads of NIOSH, NIEHS, FDA, EPA, CPSC, and the Secretary of Labor as *ex officio* members of this board. Other members of the board (18 are appointed by the President and 11 are *ex officio* members) represent the academic world, the public, and other Federal agencies. The NCAB not only receives and reviews reports on progress and plans from the National Cancer Institute, but has also established several subcommittees to analyze and report on particular issues of interest to the board. The National Cancer Advisory Board, composed of government and nongovernment representatives, advises NCI on policies regarding cancer research and other related issues, and thereby serves a coordinating function both within the government, and between the government and people outside government.

The Executive Office of the President, through its review and oversight functions, helps to coordinate the various cancer-related programs administratively. Such coordination particularly occurs with the budget and program reviews carried out annually by the Office of Management and Budget. The preparation of the Administration's proposed budget and the review and approval of proposed legislation both involve interagency coordination, and are necessarily fundamental steps in defining and coordinating all aspects of the government's cancer policy.

The Administration will also initiate special policy coordination reviews. An example is the Toxic Substances Strategy Committee (TSSC) which was established by the President in his 1977 Environmental Message. This committee, which is in the process of completing its work, was established (1) to eliminate overlaps and fill gaps in the collection of data on toxic chemicals, and (2) "to coordinate Federal research and regulatory programs affecting them."[2] The committee is chaired by the Chairman of the Council on Environmental Quality (in the Executive Office of the President), and includes 17 agencies involved in the effort to control toxic substances. The TSSC adopted a work plan and established work groups to deal with many of the issues involved in regulating carcinogens.[3] The reports of the work groups were summarized in the committee's final report which has been released in draft form for public comment.[4]

A third example of such coordination efforts is the Regulatory Council established by President Carter in October 1978. This council, composed of 35 departments and agencies with significant regulatory responsibilities, was created to coordinate the activities of the regulatory agencies and to assist them in implementing their regulatory programs in a consistent and cost-effective manner. Nineteen independent regulatory agencies also contribute to the council's activities in various ways. The first responsibility of the council was to prepare a "regulatory calendar" which summarized the important Federal regulations under development.[5] The council will also undertake various other policy and procedural coordination efforts related to the regulation of carcinogens.

An example of coordination efforts instituted by the agencies themselves is the Interagency Regulatory Liaison Group (IRLG). This is perhaps the most ambitious of such coordinating efforts. It was formed in 1977 by four agencies—the Consumer Product Safety Commission, the Environmental Protection Agency, the Food and Drug Administration, and the Occupational Safety and Health Administration, and was expanded in December, 1978, to include the Food Safety and Quality Service of the Department of Agriculture. All five agencies are responsible for regulating hazardous substances—protecting people from excessive exposure to such substances in their food, drugs, consumer goods, workplace, and in the air and water. The IRLG established a series of work groups and task forces to deal with many of the regulatory and research issues which affect the agencies, both at headquarters and in each of the 10 Federal regions. These groups have been

[1] For example, section 9 of the Toxic Substances Control Act and section 29 of the Consumer Product Safety Act.

[2] The President's Message to the Congress on the Environment, May 23, 1977, Section I.

[3] (42 FR 57866).

[4] (44 FR 48134, Part IV).

[5] The first calendar was published on Wednesday, February 28, 1979 (44 FR 11388).

carrying out projects which are directly related to ensuring better coordination of carcinogen regulatory programs.

A closely related effort, the National Toxicology Program (NTP), was established in November, 1978, by the Department of Health, Education, and Welfare to coordinate the activities of HEW's several institutes and bureaus devoted to toxicological research and testing. The broad goal of this program is to strengthen HEW's activities in the testing of chemcials of public health concern, as well as in the development and validation of new and better integrated test methods. At present the NTP is comprised of the relevant activities of the Food and Drug Administration (FDA), the National Cancer Institute (NCI), the Center for Disease Control/National Institute for Occupational Safety and Health (NIOSH), and the National Institute of Environmental Health Sciences (NIEHS). In order to ensure that these activities within HEW are coordinated with the needs and activities of the regulatory agencies, the original four IRLG agencies are members of the program's executive committee.

The coordinating programs described above are some of the more important and broader ranging efforts. However, a number of less extensive coordinating mechanisms have been established to deal with specific issues. These, and the particular activities of the broader programs, are described in the remainder of this annex.

Identifying Carcinogens

Much of the effort to coordinate carcinogen policies has focused on the scientific issues involved in testing carcinogenic substances and assessing carcinogenic risks. As a result, this is the general area in which most progress has already been made. The IRLG has focused many of its activities in this area and the National Toxicology Program was established to bring about further coordination. In addition, there have been a number of administrative and legislative efforts at coordination that have focused in this area.

Research

A number of different government agencies have developed significant research programs to gain a better understanding of carcinogens and the way in which they affect humans. The largest programs are sponsored by the National Cancer Institute, the National Institute of Environmental Health Sciences, the National Institute of Occupational safety and Health, the Environmental Protection Agency, the Food and Drug Administration, the Department of Energy, the Department of Defense, the Department of Commerce, and the Department of Agriculture.

According to one tabulation, these agencies spent a total of approximately $400 million dollars in FY 1977 in research related to toxic substances, a large proportion of which was focused on the problem of cancer and carcinogens.[6]

These research programs tended to develop in a largely uncoordinated fashion, but during the past year there have been several major efforts to gain a better understanding and improve the coordination of different agencies' research programs. The first of these was the IRLG Research Planning Work Group. This group tabulated all the toxics research being sponsored by the four IRLG agencies plus three research institutes (NCI, NIEHS, and NIOSH) and analyzed this information to try to identify areas of overlap or particular gaps in the research programs. They did not isolate cancer-related research but analyzed it along with their other toxics research. They discovered few instances of possible research overlaps, but did identify some potentially serious research gaps.

A similar effort was initiated by the Toxic Substances Strategy Committee covering more agencies than the seven included in the IRLG's effort. This analysis was based upon the information collected by the IRLG Research Planning Work Group, the Smithsonian Institution's Scientific Information Exchange System, and special submissions by individual agencies. Again, there was no specific focus on cancer-related research, although it was included with the other toxics research. Like the IRLG effort they found little evidence of duplication, but some possibly significant gaps.

Concern about the budgetary coordination of toxics-related research led the Office of Management and Budget to initiate a cross-agency "Zero-Based Budget" (ZBB) exercise for the 1980 budget year. This exercise included the same agencies in the IRLG effort (the four IRLG agencies, NCI, NIEHS, and NIOSH). For this exercise each agency divided its research into "decision units" which were ranked jointly by all the agencies according to commonly agreed upon criteria relating primarily to the quality and importance of the research. Again, there was not particular focus on cancer-related research, and no effort was made to obtain a specific understanding of what was being done in this subject area.

The fourth effort, the National Toxicology Program, is focusing more on developing an ongoing management system for planning and coordinating research done under different auspices within HEW. This program was given authority to plan use of part of the research budget for four agencies—NCI, NIEHS, NIOSH, and FDA. The program does not cover all of the cancer-related research, but does include most of that testing within HEW directly relevant to the identification of carcinogens. In order to ensure that the HEW research plans are coordinated with the research and information needs of other agencies, three of these agencies (EPA, OSHA, and CPSC) are members of the Executive committee which reviews the program plans.

The National Toxicology Program is related to a broader Department of Health, Education and Welfare coordination effort, the Committee to Coordinate Toxicology and Related Programs. This committee provides advice to the department on toxicological activities and serves to coordinate the exchange of information and the sharing of resources among agencies in the department. Although established within HEW, it includes liaison members from most other Federal agencies having significant interests in toxicology, and thus serves as a focus for more general information exchange and coordination.

Two other research planning, advising, and coordinating efforts also deserve mention. These include the National Cancer Advisory Board and the NCI Clearinghouse for Environmental Carcinogens. Each of these efforts is primarily concerned with the programs and activities of the National Cancer Institute. However, each accomplishes some important coordination among agencies. Their membership includes representatives from other agencies and the public. The National Cancer Advisory Board reviews all research applications submitted to the National Cancer Institute, and, in addition has a subgroup focusing upon environmental carcinogenesis. The NCI clearinghouse, which includes even broader representation from other agencies, is concerned with planning and advising on test methods and priorities and with evaluating the results of NCI's testing and associated risk assessments.

Testing Priorities

In the past, each of the agencies doing carcinogenesis testing tended to set its

[6] Toxic substances Strategy Committee, "Toxic Substances: A Review of Federal Research, Development, Testing and Monitoring Activities," August 1978.

own testing standards and establish its own priorities.

Some consistency in priority setting was accomplished through various advisory committees, of which NCI's Clearinghouse on Environmental Carcinogenesis was perhaps the most important. Although NCI and other testing agencies did attempt to respond to regulatory needs when they were expressed, the regulatory agencies often did not have strong inputs to those committees.

The creation of the National Toxicology Program has established a more vigorous forum for coordinating testing priorities. This program is developing criteria for setting testing priorities which reflect the needs of both the regulatory agencies and the research institutes. The regulatory agencies, represented on the program's Executive Committee, will also have a stronger role in selecting the specific substances tested for all of the HEW testing programs covered by the NTP.

Another major program established to coordinate testing is the Interagency Toxic Substances Testing Committee. This committee was established by section 4(e) of the Toxic Substances Control Act of 1977, and includes members from eight agencies involved in regulating toxic substances. Its role is to review current knowledge of the potential toxic effects of different substances, and recommend to EPA which of these substances should receive highest priority for testing. EPA then reviews these recommendations in terms of the priorities it will establish for tests to be conducted by industry under section 4 of the Act.

The National Toxicology Program and the Interagency Toxic Substances Testing Committee substantially improve the amount of coordination occurring on setting testing priorities. The National Toxicology Program will serve to coordinate testing priorities among the research agencies and the regulatory agencies, and the testing committee will serve to coordinate priorities between the government and private sector. Coordination between these two efforts results from having the same agencies represented on both.

Conduct of Studies

Typically, when laboratory testing is as diffused and is changing as rapidly as it is in the case of cancer research, a number of different experimental methods tend to come into use. To a large extent this is desirable, for it allows for development of new equipment and techniques, and often results in discovery of more efficient and accurate procedures. However, for the purpose of making regulatory decisions, the agencies must have confidence in the quality of the testing, and in the consistency of test results.

Efforts to promote such quality and consistency can take several forms. The first stage is usually the development of suggested analytical methods for use within an agency. Some of these will be adopted by other agencies as well. For instance, the National Cancer Institute has prepared manuals containing recommended testing methods for determining carcinogenesis. The National Academy of Sciences, the World Health Organization, FDA, and EPA have also prepared such manuals.

As more experience is gained with the different methods, the agencies begin to agree on what the preferred methods are. In the second stage of coordination, the different agencies adopt consistent methods. Thus, HEW prepared regulations defining Good Laboratory Practices, and during the past year these have also been accepted by EPA, CPSC, FDA, and OSHA. This has represented a significant step forward in consistency and quality control.

An associated problem is being addressed by the IRLG Work Group on Testing Standards and Guidelines. This work group is addressing the problem that would be created if the different agencies where to require slightly different testing procedures, all of which might be equally acceptable from the standpoint of quality control, to be used in conjunction with their specific regulatory programs. These differences can cause confusion and unnecessary costs by requiring a firm to undertake somewhat different tests on the same substance when trying to satisfy different regulatory requirements. The IRLG Testing Standards and Guidelines Work Group is attempting to avoid this problem by developing one set of testing standards that will be accepted by all the IRLG agencies.

The IRLG Epidemiology Work Group is attempting to accomplish some of the same improvements with respect to epidemiological studies. However, this group is focusing more on defining the minimal characteristics of epidemiological studies than in defining study protocols similar to those being developed by the Testing Standards and Guidelines Work Group.

Similar coordination of testing methods is occurring in the international context through the Organizations for Economic Development and, to a lesser extent, United Nations' associated organizations such as the World Health Organization and the Food and Agriculture Organization.

Identifying Carcinogens

With the profusion of different testing and regulatory programs, there has been some concern that different agencies will make inconsistent assessments of the potential carcinogenicity of a particular substance. This concern has created a substantial interest during the past 2 years in developing procedures for ensuring that these qualitative assessments of risks are consistent.

One of the more ambitious of these efforts was the report prepared by the IRLG Risk Assessment Work Group entitled "Scientific Bases for the Identification of Potential Carcinogens and the Estimation of Risks."[7] This document represents the judgment of the agency scientists on the scientific concepts and methods used to identify and evaluate substances that pose a risk of cancer to humans. The document describes the bases for making a qualitative evaluation of whether a particular substance presents a carcinogenic hazard, and how the results of epidemiological studies and animal bioassays, along with other types of information, are to be used in making that evaluation. The document is currently receiving public and scientific review and comment.

Several other efforts in the government have also addressed this issue. The National Cancer Advisory Board's Committee on Environmental Carcinogenesis is preparing a document which is similar to that prepared by the IRLG. The Office of Science and Technology Policy, in the Executive Office of the President, has also prepared a similar document.

Another step to promote consistency is the effort by the National Cancer Institute to disseminate the results of its carcinogen assessments. This is done through the Clearinghouse on Environmental Carcinogenesis and via an annual report on Carcinogens NCF is required to make to Congress under a recent amendment to the National Cancer Act.[8]

Assessing Human Risk

Most of the government's attention on issues relating to the assessment of human risk has been focused on the appropriateness and methodologies for making quantitative risk estimates.

A number of different estimation techniques have been proposed and used without general agreement about their accuracy and reliability. Because of the substantial uncertainties

[7] (44 FR. 39858–39879) and *Journal of the National Cancer Institute*, Vol. 63, No. 1 (July, 1979), pp. 241–268.

[8] Pub. L. 95–622, Title II, Part E, section 282.

involved, it is probably not possible to determine whether a specific estimation technique. is correct. It is nevertheless desirable for all agencies using quantitative estimates in their regulatory programs to make such estimates consistently.

A major purpose of the IRLG Risk Assessment Work Group was to provide a framework for this consistency. Their report ("Scientific Bases for the Identification of Potential Carcinogens and Estimation of Risks") describes some methods that are used in making quantitative estimates of the Carcinogenic risks posed by a substance if such risk estimates are appropriate or required. The report discusses the various quantitative estimation techniques currently being used, the various problems associated with such estimation techniques, and recommends that the agencies include the results from onr particular technique when undertaking quantitative risk estimations. This document should serve both to insure that the agencies interpret data consistently and to reduce the public's uncertainty about the scientific and policy judgments that the agencies make in their interpretations.

Regulatory Policies

Until recently, most efforts to coordinate agency actions in regulating carcinogens focused upon the scientific aspects of the regulatory programs—the testing of substances, the assessment of hazards, the estimation of risks. As these become better coordinated,the emphasis is shifting—particularly with the establishment of the IRLG and The Regulatory Council—to coordinating government intervention as well. These efforts are dealing with issues such as setting regulatory priorities, agreeing upon what analyses ought to be undertaken to support regulatory decisions, coordinating specific regulatory actions, and coordinating compliance monitoring and enforcement.

Regulatory Priorities

The IRLG regulatory Development Work Group is responsible for the major efforts to coordinate regulatory priorities among agencies. It has set up a process whereby each agency is notified immediately as soon as one of the agencies begins to consider regulating a particular substance. With this arrangement the agencies are aware of one another's priorities and can reevaluate their own priorities in view of other agency plans.

Decision Analyses

The major coordination on decision analyses has resulted from Executive Order 12044 issued by President Carter[9] and The National Environmental Policy Act.

The National Environmental Policy Act requires each agency to analyze the environmental implications of those actions which may have a significant impact upon the human environment. The Council on Environmental Quality implements these provisions and has issued regulations governing the preparation and processing of environmental impact statements.[10] However, there is some variation among agencies regarding how and when they undertake environmental impact assessments related to regulatory activities.

Executive Order 12044 applies to all regulations which potentially have a major economic impact issue by agencies within the Executive Branch. It requires agencies proposing these regulations to undertake regulatory analyses which are published for review and comment. The Council on Wage and Price Stability and the Office of Management and Budget have prepared guidelines regarding the content of these analyses and the way in which they should be done.[11]

Selected regulatory analyses are also reviewed by the Regulatory Analysis Review Group (RARG). This group is chaired by the Chairman of the Council of Economic Advisors and is made up of representatives from the Office of Management and Budget and the principal Executive Branch economic and regulatory agencies. RARG reviews up to 20 regulations a year (not more than 4 from any one agency) which it believes may have a significant impact upon the economy. The implementation of Executive Order 12044 has resulted in substantial consistency with respect to the issues of when economic analyses will be conducted and what they should contain.

The IRLG Regulatory Development Work Group is also concerned with what analyses are done and how they are coordinated among the IRLG agencies. The IRLG also has a group of Senior Economists to coordinate the economic analyses carried out by different agencies and to develop common analytical tools and data bases that could be used in these analyses.

Regulatory Actions

The type of actions that regulatory agencies can take and the considerations and principles that are to be taken into account in deciding upon these actions are largely specified by Congress in the statutes establishing the various regulatory programs. However, there are several major efforts to coordinate the agencies' actions within these statutory constraints.

The IRLG agencies are attempting to coordinate their regulatory actions through the Regulatory Development Work Group. This work group has identified the hazardous substances which two or more of the IRLG agencies are currently considering regulating. For each of these substances the work group has established a special subgroup composed of key officials from the relevant agencies. These subgroups have the responsibility for coordinating the actiities of the various agencies, ensuring that they are consistent with one another and informing the public on what each of the agencies is doing. As part of this effort they have prepared a document entitled *Hazardous Substances* which lists 24 substances; summarizes what is known about their health effects, production, and use; lists the regulatory authorities under which action is being taken or considered; indicates certain regulatory issues that have arisen; and sets forth the agencies' proposed schedule of regulatory activities.[12] The information in this document is being updated semi-annually by an IRLG publication entitled *Regulatory Reporter.*[13]

The Regulatory Council's "regulatory calendar" should also serve as an important coordinating mechanism.[14] The calendar contains a listing of all the important rules and regulations that the agencies are working on, the benefits and costs anticipated to result from the agency's regulatory action, and the alternative actions being considered. The preparation and public release of this calendar should serve to increase the consistency of agency interventions. In addition, the staff of The Regulatory Council will examine the submissions to

[9]Executive Order 12044, "Improving Government Regulations," issued by the President on March 23, 1978 (42 FR 59790).

[10]43 FR 55978 (November 29, 1978, Pt. 6).

[11]Memorandum from Wayne G. Grinquist, Associate Director, Management and Regulatory Policy, Office of Management and Budget to the "Heads of Departments and Agencies." Subject: Guidance for Regulatory Analysis, dated November 21, 1978.

[12]Interagency Regulatory Liaison Group, *Hazardous Substances* (Washington, D.C., U.S. Government Printing Office, December 1, 1978).

[13]Interagency Regulatory Liaison Group, *Regulatory Reporter,* Vol. I, Issue 1, published June, 1979 (Washington, D.C., U.S. Government Printing Office).

[14]The first calendar was published in the *Federal Register* on February 28, 1979, a 44 *Federal Register* 11388–11516.

identify possible conflicts, inconsistencies, or instances of overlap.

Executive Order 12044 (and NEPA, where applicable) also requires agencies to analyze proposed interventions and the reasonable alternative means of intervention in the economic (or environmental) impact statements they are required to prepare. The economic impact statements are reviewed by the Council on Wage and Price Stability which attempts, among other things, to identify any inconsistencies among the agencies. Where potentially serious inconsistencies appear, the proposed intervention may be referred to the Regulatory Analysis Review Group for more intensive consideration.

The potential for coordination and the benefits that can result if the agencies do work closely together were clearly demonstrated in the regulation of chlorofluorocarbons. Chlorofluorocarbons were at one time used extensively as propellants in aerosol sprays, among other uses. They were found, however, to be causing a potentially serious depletion of ozone in the atmosphere.

Various scientific studies demonstrated that such depletion could have very serious long-range impacts on health and the environment. Three agencies, EPA, CPSC, and FDA, had partial jurisdiction. When it became evident that there was a potentially serious problem, these agencies met together to consider possible regulatory responses. As a result, they developed a joint regulatory approach that embodied agreement on the actions that each of the agencies would take and the timing of these actions. This arrangement resulted in one of the agencies (CPSC) agreeing to take no action at all because it would have done little more than duplicate what the regulations of the other two agenices would accomplish. This cooperation enabled the three agencies to announce jointly what each of them would be doing and when, eliminating any uncertainty about the specific interventions that were planned. The agencies also jointly undertook to sponsor additional research on the problem to determine whether further actions with respect to nonaerosol uses of cloroflurocarbons were needed and how any such intervention could most efficiently occur.

Monitoring

Ambient and compliance monitoring are important aspects of any regulatory program. Ambient monitoring involves identifying the existence of potential carcinogens in places—e. g., the air, food products, consumer products, the workplace—where people may be exposed to them. Compliance monitoring involves determining whether sources of these contaminants are complying with regulations to control people's exposure to such substances.

In the past, the main coordination of monitoring has resulted from the regulatory agencies using data collected by other data-collecting agencies such as HEW's Center for Health Statistics. Recently, the coordination of ambient monitoring has been looked at in greater detail by an interagency committee established by the Council on Environmental Quality to review environmental data and monitoring, by the Interagency Toxic Substances Data Committee, by the IRLG Information Exchange Work Group, and by the Office of Management and Budget. Various efforts have also been undertaken to coordinate compliance monitoring through the IRLG Compliance and Enforcement Work Group and various regional IRLG organizations.

The President established the CEQ Interagency Task Force on Environmental Data and Monitoring in his Environmental Message of May, 1977.[15] This task force has undertaken an extensive review of the government's efforts to monitor air pollutants, water pollutants, and other environmental characteristics. However, it has deferred consideration of carcinogen and toxics monitoring to the Interagency Toxic Substances Data Committee.

The Interagency Toxic Substances Data Committee was established by section 4(e) of The Toxic Substances Control Act. Its purpose is to facilitate the exchange of information on toxic substances among agencies. Although the focus is on information exchange, it must also consider who should collect the information and how they should collect it. The issues being addressed by this interagency committee are closely coordinated with those being addressed by the IRLG Information Exchange Work Group, which serves a similar role among the IRLG agencies. However, neither of these efforts has yet led to an intensive effort to improve the coordination of ambient monitoring activities by the different agencies.

The coordination carried out by the Office of Management and Budget occurs primarily with respect to the budget submissions of the individual agencies and to the clearance of the forms which will be used to collect the information. The coordination of data collection efforts is further emphasized in The Regulatory Reform Act of 1979 submitted to the Congress by the President in March, 1979.

There is, however, a significant increase in the coordination of compliance monitoring by the agencies. In the agencies' regional offices, inspectors from each agency are being educated about the programs of the other agencies. A process for referring possible violations of another agency's regulations to that agency has also been instituted. The IRLG Compliance and Enforcement Work Group has developed the educational materials and the forms being used in this effort. This work group is also exploring the possibility of such further coordination as joint inspections (where inspectors from different agencies inspect a site jointly) and cross-over inspections (where the inspectors from one agency inspect for other agencies as well as their own).

An important contribution to such coordination may result from a demonstration project in New Jersey conducted by the Environmental Protection Agency in association with the IRLG Information Exchange Work Group. A serious hurdle to better coordination has been that the different agencies, and often different programs within the same agency, do not use the same means for identifying individual facilities being controlled. The New Jersey project is exploring the feasibility of developing a "common code" system of identifying facilities. If such codes were used to identify facilities and sites, one could quickly identify how each agency is involved with any particular facility or site, when any agency last inspected the facility, whether any and what type of violations have been found, etc.

Enforcement

The primary coordination of enforcement policies is occurring through the IRLG Compliance and Enforcement Work Group and IRLG cooperation among the regional offices. In addition to the training of inspectors and the referral of violations, there has been increased mutual support of enforcement actions through the sharing of laboratory facilities, information, and expert witnesses among agencies, and by the agencies undertaking special investigations for one another.

Agency coordination is also important in responding to emergency episodes, such as spills or plant accidents, involving the release of toxic chemicals. The Toxic Substances Strategy Committee established a special subcommittee to address this problem. It has concentrated upon improving the response capacity at the State and local

[15] The President's Message to Congress on the Environment, May 23, 1977.

levels, better organizing EPA's response system, and achieving better coordination between EPA, the Department of Transportation, and the private sector. In addition, the IRLG agencies have developed, at both regional and headquarters levels, emergency notification schemes and emergency response plans to deal with such episodes. These are currently being integrated with the national response system established by The Clean Water Act (involving the Council on Environmental Quality, the Department of Transportation, and EPA) to respond to oil and hazardous substances spills.

Conclusion

This appendix describes some of the ongoing coordination efforts which are most relevant to the regulation of carcinogens. Additional efforts are also occurring in areas less directly related. Further information about the activities of the major coordinating efforts can be obtained by contacting the following:

Interagency Regulatory Liaison Group, 1111 18th Street, NW. (Room 509), Washington, D.C. 20207.

The Regulatory Council, New Executive Office Building, 726 Jackson Place, NW., Washington, D.C. 20460.

National Cancer Advisory Board, National Cancer Institute, Public Health Service, U.S. Department of Health, Education, and Welfare, 900 Rockville Pike, Bethesda, Maryland 20014.

National Toxicology Program, National Institute of Environmental Health Sciences, Public Health Service, Department of Health, Education, and Welfare, Bethesda, Maryland 20014.

Table 1—Interagency Coordination Efforts

Overall Coordination Efforts

Office of Management and Budget:
- Budget preparation
- Legislative clearance

Toxic Substances Strategy Committee (TSCC)

Regulatory Council

Interagency Regulatory Liaison Group (IRLG)

Committee to Coordinate Toxicology and Related Programs (HEW)

National Toxicology Program (NTP)

National Cancer Advisory Board

Identifying Carcinogens

Research:
- IRLG Research Planning Work Group
- TSSC
- Interagency Toxic Substances Zero Based Budget Analysis
- NTP
- National Cancer Advisory Board
- National Cancer Institute Clearinghouse for Environmental Carcinogens
- IRLG Preventive Health Initiative
- CCTRP
- Interagency Collaborative Group on Environmental Carcinogens

Testing Priorities:
- NTP
- Interagency Toxic Substances Testing Committee
- NCI Chemical Selection Committee

Conduct of Studies:
- Manuals of recommended testing procedures (e.g., NCI)
- Good Laboratory Practices
- IRLG Testing Standards and Guidelines Work Group
- IRLG Epidemiology Work Group
- Various international efforts

Assessing Human Risk:
- IRLG Risk Assessment Work Group
- Office of Science and Technology Policy
- NCI Clearinghouse on Environmental Carcinogens
- Annual Report of NCI
- National Cancer Advisory Board Committee on Environmental Carcinogens

Regulatory Policies

Regulatory Priorities:
- IRLG Regulatory Development Work Group
- TSSC

Decision Analyses:
- National Environmental Policy Act
- Executive Order 12044
- Regulatory Analysis Review Group (RARG)

Regulatory Actions:
- IRLG Regulatory Development Group
- Regulatory Council
- Executive Order 12044

Monitoring:
- Control Data Collection Agencies, Center for Health Statistics
- Interagency Toxic Substances Data Committee
- IRLG Information Exchange Work Group
- Office of Management and Budget
  - Survey clearance functions
  - Budget preparation
- IRLG Compliance and Enforcement Work Group
- IRLG regional activities

Enforcement:
- IRLG Compliance and Enforcement Work Group
- IRLG regional activities
- TSSC
- National Response System

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